and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(b) These officials may not further redelegate this authority.

§ 5.411 Medical device recall authority.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), which have been delegated to the Commissioner of Food and Drugs:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.412 Temporary suspension of a medical device application.

(a) The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(e)), to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(4) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.413 Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation

and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act (21 U.S.C. 360j(y)).

(c) The following officials are authorized to enter into written agreements concerning investigational device exemption protocols under section 520(g)(7) of the act (21 U.S.C. 360j(g)(7)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(3) The Director, Program Operations Staff, ODE, CDRH.

(4) The Chief, Investigational Device Exemption Section, ODE, CDRH.

(5) For medical devices assigned to their respective Divisions: The Division Directors and Deputy Division Directors, ODE, CDRH.

(6) The Director and Deputy Directors, CBER, and the Director and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH and the Director and Deputy Directors, ODE, CDRH, the Director and Deputy Directors, CBER, and the Director and Deputy Directors of the OBRR, OVRR, and OTRR, CBER, are authorized to make decisions under section 520(g)(7) of the act (21 U.S.C. 360j(g)(7)) with respect to an agreement on an investigational plan, that a substantial scientific issue essential to determining the safety and effectiveness of the device involved has been identified.

(e) These officials may not further redelegate these authorities.

§ 5.414 Postmarket surveillance.

(a) For any class II or class III device (including any device that is or contains a drug or biologic), the failure of which would be reasonably likely to have serious adverse health consequences, or which is intended to be implanted in the human body for more than 1 year, or a life supporting or life sustaining device used outside a user facility, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics (OSB), and the Director, Issues Management Staff, OSB, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Science and Technology, CDRH.

(6) The Director and Deputy Director, Office of Health and Industry Programs, CDRH.

(7) The Director and Deputy Director, Office of Compliance, CDRH.

(8) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(9) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(10) The Director and Deputy Director, Office of Compliance, CDER.

(11) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(12) The Director and Deputy Director, Office of Compliance and Biologics Quality, CBER.

(13) The Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate these authorities.